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SERIAL NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTORNEY DOCKET NO.
08/455,426	05/31/95	BARNIKOL	W DT-1216

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18N2/0529

GUPTA, R. EXAMINER	
ART UNIT	PAPER NUMBER
1811	5

DATE MAILED: 05/29/96

Please find below a communication from the EXAMINER in charge of this application.

Commissioner of Patents

SEE ATTACHED.

Office Action Summary

Application No.
08/455,426

Applicant(s)
Wolfgang Barnikol

Examiner
Anish Gupta

Group Art Unit
1811



☐ Responsive to communication(s) filed on _____.

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1-5 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 1-5 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☒ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☒ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

Claim Rejections - 35 USC § 112 *Second Paragraph*

1. Claims 1-5 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-5 are unclear as they are currently written. Currently, the claims recite various steps for the preparation of hyperpolymeric hemoglobin and then state to use a "combination of one or more of the above". However, it is unclear whether the steps recited in the claims are all mandatory or if they can be used alone or in combination with one another. For example, it is unclear in claim 1 whether the claim recites to perform all of the purification methods, ultrafiltration, fractional precipitation, chromatography, and partial dissolution for the preparation of molecularly uniform hyperpolymeric hemoglobin or just if the claims only requires one or a combination of one or more to be performed?

Claim 3 recites the utilization of "different agents" for the fractional precipitation. The phrase "different agents" is vague and indefinite.

Claim Rejections - 35 USC § 112 *First Paragraph*

2. The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The specification is objected to under 35 U.S.C. § 112, first paragraph, as failing to provide a written description.

In claims 3 of the instant application, it states that "different agents" or "precipitating agents" are used for the fractional precipitation and in claims 5 it states that stabilizing agents are used to treat the dissolving polymers. However, the specification fails to state exactly what are all of the different "agents" are used for precipitation and stabilizing the polymer. The examples given in the specification do not provide such missing information. Without such information one of ordinary skill in the art could not predict what could be considered and used as precipitating agents and/or stabilizing agents.

Claims 3 and 5 are rejected under 35 U.S.C. § 112, first paragraph, for the reasons set forth in the objection to the specification.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 1-2 and 4 are rejected under 35 U.S.C. § 102(a) as being anticipated by Barnikol (Artificial Cells Blood Substitutes and Immobilization Biotechnology).

The reference teaches the purification of hyperpolymeric hemoglobin, cross-linked with DIBS, using chromatographic techniques and ultrafiltration (see page 727, Material and Methods).

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --
(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1 and 4 are rejected under 35 U.S.C. § 102(b) as being anticipated by Barnikol (Adv. Exp. Med. Biol.).

The reference teaches the purification of hyperpolymeric hemoglobin using thin layer chromatography (see page 131, Experiments, Results and Discussion section).

5. The prior art made of record, u,u1, and x, and not relied upon is considered pertinent to applicant's disclosure.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anish Gupta whose telephone number is (703) 308-4001.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Beth Wiemar, can normally be reached on (703) 308-3804. The fax phone number of this group is (703) 308-3014.

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Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Elizabeth C. Weimar
ELIZABETH C. WEIMAR
SUPERVISORY PATENT EXAMINER
GROUP 1800